performed to detect Atopobium vaginae (Av), Sneathia sanguinegens (Ss), Leptotrichia amnionii (La) and Gardnerella vaginalis (Gv), and with SYBR green assays for BVAB 1, 2 and 3, and Megasphaera phylotype 1 (M1).

Results Gv was detected in 93% of cases with UUE and in 37% of controls ($p<0.0001$). There was no difference in organism load. In the 28 NGU cases Av, Ss and La were found in 3, 2 and 1 samples, respectively, and in 6, 2 and 1 of the control samples, respectively. The median corresponding organism loads were 14, 95 and 51 for the NGU cases and 16, 10 566 and 353 for the controls. All samples were negative for BVAB 1, 2 and 3 and M1, except one control with 10 genome copies of BVAB 1.

Conclusions *Gardnerella vaginalis* was associated with male urethritis in this study, especially in men with asymptomatic urethritis, while BVAB 1, 2 and 3, Megasphaera phylotype 1, *Atopobium vaginae*, *Sneathia sanguinegens*, and *Leptotrichia amnionii* were not.

P3-S1.29 EFFECTIVENESS OF GENTAMICIN FOR GONORRHOEA TREATMENT: A SYSTEMATIC REVIEW

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Background The development of resistance to multiple antimicrobials has limited treatment options for gonorrhoea. Potential emergence of cephalosporin resistance in *Neisseria gonorrhoeae* and cephalosporin allergy in some patients make it necessary to evaluate the effectiveness of other available antimicrobials. Gentamicin is widely available in the USA and is used for gonorrhoea treatment in several countries.

Methods We conducted a systematic review of the medical literature to assess the effectiveness of gentamicin for treatment of uncomplicated urogenital gonococcal infections. Two reviewers assessed relevant articles and independently selected studies that met prespecified selection criteria (including systematic enrolment and assignment to treatment and culture-confirmed diagnosis and outcome). Summary measures for selected studies were pooled using inverse variance-weighted averages with fixed effects. Heterogeneity was assessed using I-squared, which estimates proportion (from 0% to 100%) of variability attributable to heterogeneity between studies. Pooled percentage with negative follow-up culture was compared with CDC criteria for selection of recommended therapy (>95% efficacy with lower 95% CI >95%).

Results 18 potentially relevant English-language studies were identified; three met inclusion criteria. Reviewer agreement for initial judgement on meeting selection criteria was substantial (κ 0.68). Two studies used 240 mg, and one study used 280 mg IM gentamicin. Percentages with negative culture after single-dose treatment were 90.7% (n=86), 91.4% (n=220), and 95.0% (n=40). Pooled percentage with negative culture after single-dose treatment was 91.5% (95% CI 88.1% to 94.0%, I-squared = 0%).

Conclusions Gentamicin does not meet current CDC criteria for recommended treatment of gonorrhoea. However, if cephalosporin resistance emerges, gentamicin may be a useful alternative agent. Evaluation of additional regimens, including combination therapy, is warranted.

P3-S1.30 SUCCESSFUL USE OF NON-INVASIVE SELF OBTAINED GLANS/MEATAL DRY FLOQSWABS (COPAN) FOR CT/NG DETECTION WITH THE BD PROBETEC ET ASSAY IN NORTHERN ITALY

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Background Increasing *Chlamydia trachomatis* (CT) rates and ever-present *Neisseria gonorrhoeae* (NG) infections worldwide in women have led to the consideration of targeted male CT/NG screening programs in order to address the male reservoir. Effortlessly collected, non-invasive, painless, dry, self-obtained male swab specimens that are stable and easy to transport would enhance the success of male screening programs. We undertook a study to compare the results of self obtained glans/meatal swab (SOGS) (COPAN FLOQSwabs) specimens with conventional first catch urine (FCU) specimens. The aim of the study was simply to assess the usefulness of a SOGS specimen when compared to FCU given the SOGS specimen's ease of collection, ease of use and handling in challenged venues (ie, without toilet facilities), and ease of transport.

Methods 122 male patients attending an STD clinic and males incarcerated near the Italian city of Asti were tested for CT and NG using a SOGS. Patients were verbally instructed and shown a drawing to enhance standardised self-collection. A FCU specimen was also collected. SOGS and FCU specimens were then processed according to the manufacturer's recommended procedure using the BD ProbeTec ET system (Becton Dickinson and Company).

Results There were a total of 16 specimens detected positive for either CT or NG. Seven men were infected by both CT and NG. The CT prevalence was 5.7%. The NG prevalence was 13.1%. There was an overall SOGS specimen agreement of 97.5% when compared to FCU specimen results.

Conclusions High agreement was obtained with the self obtained glans/meatal COPAN FLOQSwabs when compared to standard FCU specimens. These results indicate that self obtained glans/meatal swab specimens are a viable specimen choice. Dry self obtained glans/meatal swab specimens with FLOQSwabs were easy to collect, transport and test using the BD ProbeTec ET system. The BD ProbeTec ET system showed high agreement when testing both of these specimen types. Simpler methods of collection and transport that produce reliable test results may increase the potential for screening difficult to test male populations, especially those who never test.

P3-S1.31 COMPARISON OF COPAN URISWAB WITH BD PROBETEC URINE PRESERVATIVE TRANSPORT KIT FOR PRESERVATION AND DETECTION OF CT AND NG IN THE PROBETEC ASSAY

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Background Urine specimen collection is better accepted by the patients than invasive collection techniques for detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). Self-collection is useful for Sexually Transmitted Infection (STI) screening programs. Dedicated urine collection devices for molecular assay are unsuitable for other molecular assays and for bacteria culture investigation. Urine collection devices that are easy to collect and transport and are leak proof, that can be used for STD screening by culture and molecular assays are essential. Copan has introduced the UriSwab (US), that consists of a leak proof tube with a screw cap containing a plastic stick with sponges attached that absorb and retain the urine sample during transport while preventing bacterial overgrowth. The objective of this study was to compare the Copan UriSwab for collection, transportation and preservation of first catch urine (FCU) specimens to the BD ProbeTec Urine Preservative Transport Kit (UPT) for the detection of CT and NG with the BD ProbeTec assay.

Method FCU specimens were self-collected from 134 male patients attending an STD clinic or who were residents of a detenction center in the Italian city of Asti. Duplicate FCU specimens were collected, one with the US and the other with the UPT. The US specimens were centrifuged and the urine pellets were eluted with

ProbeTec lysis buffer. US and UPT urine specimens were processed according to the manufacturer's recommended procedure with the BD ProbeTec ET assay (Becton Dickinson).
Results Out of 134 males from the detention center and the STD clinic, 115 were negative and 19 positive for either CT or NG in both US and UPT collection devices. Five patients were positive for both CT and GC. The CT prevalence was 8.2 %. The NG prevalence was 10.44%.
Conclusions Good results agreement was found between the Copan UriSwab and the BD urine collection devices for the detection of CT and GC with the BD ProbeTec ET assay. The UriSwab is easy to transport and process in the laboratory for the detection of CT, GC and other STI infectious agents with molecular assays and can also be used for culturing all urogenital bacteria. The UriSwab can facilitate self-collection for STI screening.

P3-S1.32 A VALIDATION STUDY OF THE GEN-PROBE APTIMA COMBO2 (AC2) ASSAY FOR DETECTING *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* IN DRY SWABS

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Background Vaginal swabs are an optimal specimen for detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC). The Gen-Probe Aptima system (Aptima) requires use of a sample transport media, whereas the Becton Dickinson ProbeTec ET System (Probetec) can utilise dry swabs. The use of dry swabs allows for collection of STD test samples at non-clinical testing venues.
Methods Swabs were collected from 180 sexually active women aged 15–25 years, who had asymptomatic BV and two or more risk factors for STDs. The participants received home vaginal swab self-collection kits for BV and STD testing. Participants mailed the kits directly to the lab. Probetec swabs were tested within 14 days of collection. A dry transport swab was placed into an Aptima vaginal swab collection tube, generally within 14 days of collection and stored at −80°C. Aptima swabs were thawed and tested in batches. Specimens with discordant results in the two nucleic acid amplification test systems were retested with both systems.
Results There were 58 women (32%) positive for GC and 62 (34%) positive for CT. The level of agreement between the Aptima and Probetec systems was higher for CT (176/180, 98%) than for GC (171/180, 95%). Of the 13 samples with discordant results, five were resolved with repeat testing. All eight remaining samples had discordant GC results: seven were Probetec positive, Aptima negative and one was Probetec negative, Aptima positive.
Conclusions Vaginal swabs tested in the Aptima system were equivalent to Probetec in detecting CT but were less sensitive for the detection of GC. Dry swabs cannot be recommended for detection of GC from vaginal swabs using the Aptima system.

P3-S1.33 EVALUATION OF THE ROCHE COBAS 4800 FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* USING MINIMALLY INVASIVE SAMPLES IN WOMEN

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Background The Roche cobas 4800 (cobas) is a new diagnostic assay that utilises an automated workstation to isolate nucleic acids from clinical specimens and a real time instrument for the detection of *C trachomatis* (CT) and *N gonorrhoeae* (NG). The objective of this study was to compare the performance characteristics of the cobas to the BD Viper (Viper) and GenProbe Aptima Combo 2 (AC2) assays for the detection of CT and NG using a patient infected standard (PIS).
Methods Specimens were obtained from women attending STD, family planning, or OB/GYN clinics from 12 geographically distinct locations. Urine and vaginal swabs were obtained from each participant as were endocervical (data not shown) and liquid based cytology samples (data not shown). Women were randomised to either self-obtained (SOV) or clinician-obtained (COV) vaginal swab collection. Four sites performed testing by AC2, cobas, and Viper for urine and by cobas for vaginal swabs. A patient was considered infected if at least two of the assays with different molecular targets gave positive results from cervical or urine samples.
Results Overall CT sensitivity ranged from 91.9% to 93.9% and specificity ranged from 99.7% to 99.8% for all sample types. Overall GC sensitivity ranged from 97.0% to 100% and specificity from 99.9% to 100% see Abstract P3-S1.33 table 1.
Conclusions The cobas assay has excellent sensitivity and specificity when compared to PIS. There was no difference in performance between the SOV and COV specimens or between the vaginal and urine specimens. Self-obtained vaginal swabs provide opportunities for increased efficiency within the clinical settings. The assay is easy to perform, automated, and can be completed in <4 h.

P3-S1.34 EVALUATION OF THE ROCHE COBAS 4800 FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* USING ENDOCERVICAL SPECIMENS

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Background The Roche cobas 4800 (cobas) is a new diagnostic assay that utilises an automated workstation to isolate nucleic acids from clinical specimens and a real time instrument for the detection of *C trachomatis* (CT) and *N gonorrhoeae* (NG). The objective of this study was to compare the performance characteristics of the cobas to the BD Viper (Viper) and GenProbe Aptima Combo 2 (AC2) assays for the detection of CT and NG using a patient infected standard (PIS).
Methods Specimens were obtained from women attending STD, family planning, or OB/GYN clinics from 12 geographically distinct

Abstract P3-S1.33 Table 1 Sample Type Vag

Sample Type	n	CT Sensitivity [95% CI]	CT Specificity [95% CI]	n	NG Sensitivity [95% CI]	NG Specificity [95% CI]
Urine	4271	**92.3%** (251/272) [88.5 to 94.9]	**99.7%** (3989/3999) [99.5 to 99.9]	4274	**98.5%** (64/65) [91.8 to 99.7]	**99.9%** (4206/4209) [99.8 to 100]
SOV	2083	**93.9%** (123/131) [88.4 to 96.9]	**99.7%** (1946/1952) [99.3 to 99.9]	2083	**97.0%** (32/33) [84.7 to 99.5]	**100%** (2049/2050) [99.7 to 100]
COV	2165	**91.9%** (125/136) [86.1 to 95.4]	**99.8%** (2024/20 290) [99.4 to 99.9]	2164	**100%** (33/33) [89.6 to 100.0]	**100%** (2130/2131) [99.7 to 100.0]